OIPE JC161 MAR 2 3 2005 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of

NEVERMANN, et al.

Group Art Unit: 1617

Application No. 09/831,216
US national app. of PCT/EP99/07151

Examiner: San Ming R. Hui

Filed: April 27, 2001

For: AGENT FOR REPELLING AND INACTIVATING PATHOGENIC ORGANISMS OF PLANTS

* * * * *

DECLARATION UNDER 37 CFR 1.132

Hon. Commissioner of Patents
And Trademarks
P.O. Box 1450
Alexandria, VA 22313

Sir:

I, Dr. Jutta Höffler, a citizen of Germany, declare as follows:

1. I am employed by Technische Mikrobiologie, located at Ahrensburger Straße 162, 22046 Hamburg, Germany, where I am a General Manager.
2. At the request of the applicant of the above-referenced U.S. patent application, I conducted tests to compare the disinfecting agent identified in claim 11 of the above-referenced patent application (identified as "Menno-Florades" below), with formulations of the prior art, namely:

   Example 6 of U.S. patent 4,414,128 (at column 10),

   Example 5d of International publication WO 96/11572,

   Example 6e of International publication WO 96/11572,

   Example 8 of International publication WO 96/11572, and

   Example 10b of International publication WO 96/11572.

3. The Menno-Florades formulation contains as active agent a synergistic mixture of organic acids, anionic surfactants, glycol, monovalent alcohols and hydrotropic agents according to claim 11 in U.S. patent application 09/831,216. As the organic acid component, benzoic acid (9% by weight) was used. As the anionic surfactant, the sodium salt of an alkly $C_{12} - C_{14}$) sulfonate was used. As hydrotropic agent, cumene sulfonate as sodium or potassium salt (between 5 and 40% by weight relative to the weight of the disinfecting agent) was used. As glycols there was used ethylene glycol (between 10 to 40% by weight). As monovalent alcohols there was used a mixture of propanol-1 and propanol-2 in amounts between 6 and 60% by weight relative to the weight of the disinfecting agent.
4. As for the formulations of the prior art, Example 6 of U.S. patent 4,414,128 (at column 10), Example 5d of International publication WO 96/11572, Example 6e of International publication WO 96/11572, Example 8 of International publication WO 96/11572, and Example 10b of International publication WO 96/11572, the exact compositions are listed below in Exhibits A and B.
5. The experiments were done according to the Richtlinie für die Prüfung von Pflanzenschutzmitteln zur Desinfektion im Zierpflanzenbau, herausgegeben von der Biologischen Bundesanstalt für Land- und Forstwirtschaft (BBA) (that is, guidelines for the examination and testing of disinfectants for plant cultivation, of the Federal Biological Institute for agriculture and forestry (BBA in Germany)). This is the BBA guidelines for the official testing of plant disinfectants, 16-4, April 1986.
6. The identified prior art formulations and Menno-Florades were each tested with fusarium oxysporum (test germ of the BBA guideline, page 2), in a germ carrier test, where the carrier was made of nylon, and in the presence of 1% peat.

7. As control there was used sterilizised water and water containing an inactivation agent. As inactivation agent there was used a composition containing: 3% tween 80, 3.0% saponin, 0.3% lecithin, 0.1% histidin, 0.1 mol/L Na_2HPO_4.
8. The examination report in German is appended as Exhibit C. An English translation of the examination report, with verification of translation, is appended as Exhibit D. Exhibit B also represents a summary of the results of the examination report.
9. As shown in the examination report and in the table of Exhibit B (under the columns labeled "Re-isolate of fusarium oxysporum after a residence time of"), for all of the prior art formulations tested, there was absolutely no appreciable effect demonstrated against the parasite fusarium oxysporum. For example, in the table of Exhibit B, "3/3" indicates that from three parallel experiments, all three culture media or agar media were overgrown in spite of the use of disinfectants in total with parasites. "1/3" indicates that one of three culture media show the growth of germs—however, two culture media were without parasites.
10. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dr. Jutta Höffler: _____

Title: Dr. rer. nat (General Manager)

Date: 18.03.2005

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Exhibit A

NOTIZ

Korrigierte Fassung -

Aufgrund der Einlassungen des US Patentprüfers - San Ming R. Hui – ist es notwendig, das erfindungsgemäße Produkt - **FLORADES** (US national app. of PCT/EP9907151) - im direkten Vergleich zu den entgegengehaltenen Formulierungen aus benannten Patentschriften hinsichtlich der Wirksamkeit gegenüber Pflanzenschädlingen zu testen.

Nach Absprache mit Herrn Dr. Becker (Becker · Kurig · Straus, Patentanwälte) wurden folgende Formulierungen für die Erwiderung an den US – Prüfer als relevant bewertet:

Aus der **US – Patentschrift 4,414,128**, Spalte 10, **Beispiel 6**: (geänderte Version)

Bezeichnung	Gewichtsmenge (w/w)
Mersolat W 40 (40%ig)	10,00
(*LAS C_{11}-C_{18}*	*4,00*)
Nitrilotriessigsäure Na-Salz	6,00
Dobanol 91-8 (8EO; Shell)	2,00
ß - Pinen	3,00
Benzylalkohol (Phenylcarbinol)	1,50
Cumolsulfonat-Na	2,00
Wasser reinst	75,50
	100,00

aus der **WO 96/11572**, S.19-21, Beispiele 5d, 6e, 8, 10b:

Beispiel 5d:

Zitronensäure (reinst)	3,00
Hexylenglykol	10,00
Glyzerin	10,00
Öl in Wasser Emulsion	
oder Wasser reinst	77,00
	100,00

Beispiel 6e:

Essigsäure	10,00
Propylenglykol	30,00
Polyethylenglykol	60,00
	100,00

Fusarium Sporen

Beispiel 8:

Milchsäure	10,00
Propylenglykol	40,00
Hexylenglykol	30,00
Glyzerin	10,00
Wasser reinst	10,00
	100,00

Beispiel 10b:

Milchsäure	10,00
Propylenglykol	40,00
Hexylenglykol	30,00
Wasser reinst	20,00
	100,00

19.02.2005
WZ

Verteiler:

MENNO Chemie, Herrn Jan Nevermann
Technische Mikrobiologie Frau Dr. J. Höffler
Patentanwalt Dr. Becker, Az. 51919 (BE/BS) ✓

Bitte entfernen Sie die Notiz vom 31.01.2005 aus Ihren Akten!

Effects of MENNO-Florades (see above) and different formulations of patent specifications compared with fusarium oxysporum (testgerm of the BBA-guideline, p. 2) in a carrier test with peat loading (BBA-guideline)

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		Re-isolate of fusarium oxysporum after a residence time of	
Disinfectant (concentration)	Concentration %	1 hour	4 hours
Tap water + Neutralization agent		3/3	3/3
Tap water		3/3	3/3
Example 6 US-Patent 4,414,128, col. 10	1.0% 2.0%	3/3 3/3	2/3 2/3
Example 5d, WO 96/11572	1.0% 2.0%	3/3 3/3	3/3 3/3
Example 6e WO 96/11572	1.0% 2.0%	3/3 3/3	3/3 3/3
Example 8 WO 96/11572	1.0% 2.0%	3/3 3/3	3/3 3/3
Example 10b WO 96/11572	1.0% 2.0%	3/3 3/3	3/3 3/3
Menno-Florades *according to the present invention	1.0% 2.0%	1/3 0/3	0/3 0/3

Legend: 0/3 = none of 3 carriers was overgrown
1/3 = 1 of 3 carriers was overgrown
2/3 = 2 of 3 carriers were overgrown
3/3 = 3 of 3 carriers were overgrown

*the active agent of Menno-Florades was a synergistic mixture of organic acids, anionic surfactants, glycols, monovalent alcohols and an hydrotropic agent. As acidic component benzoic acid (9% by weight) was used. The sodium salt of an alkyl (C_{12}-C_{14}) sulfonate was used as surfactant. Cumene sulfonate as sodium or potassium salt (between 5 and 40 % by weight relative to the weight of the disinfecting agent) was used as hydrotropic agent. As glycols there was used ethylene glycol (between 10 to 40 % by weight). As monovalent alcohols there was used a mixture of propanol-1 and propanol-2 in amounts of between 5 and 60% by weight relative to the weight of the disinfecting agent.

Exhibit C

Technische Mikrobiologie
Dr. Jutta Höffler GmbH
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Prüfbericht

Richtlinie* für die Prüfung von Pflanzenschutzmitteln zur Desinfektion im Zierpflanzenbau 16-4

Auftraggeber

MENNO CHEMIE-VERTRIEB GmbH
Langer Kamp 104

22850 Hamburg

Desinfektionsmittelproben

Produkt (US nat.app. of PCT/EP9907151)	**MENNO-Florades**
Chargennummer	0004 v. 07.09.2000
Hersteller	MENNO CHEMIE-VERTRIEB
Lieferdatum	12.10.2000
Produkt-Formulierung/(US Pat.4,414,128)	**6**
Produkt-Formulierungen/(WO 96/11572)	**5d, 6e, 8, 10b**
Herstellungsdatum	19.02.2005
Lieferant	MENNO CHEMIE-VERTRIEB
Lieferdatum	25.02.2005
Lagerbedingungen	Raumtemperatur
Aussehen der Produkte:	flüssig, farblos
Wirksubstanz(en)	organische Säuren, Glykole
Vom Hersteller empfohlene Gebrauchskonzentration	1,0% - 2,0%

* herausgegeben von der Biologischen Bundesanstalt für Land-und Forstwirtschaft (BBA)

Prüfverfahren und seine Validierung

Methode	Bestimmung der fungiziden Wirkung im Keimträgerversuch, Tauchbehandlung (1.3.2 Laborprüfungen)
Keimträger	1 cm^2 große Stücke Nylongewebe (Maschenweite = 0,5 mm)
Neutralisationsmedium	Polysorbat 80 (30g/l), Saponin (30g/l) Histidin (1g/l), Lecithin (3g/l)
Wachstumsmedium	Potato Dextrose Agar (Oxoid)
Bebrütungstemperatur	25°C ± 1°C
Zeitspanne der Prüfung	2005-02-18 bis 2005-03-04

Experimentelle Bedingungen

Produktverdünnungsmittel, das bei der Prüfung benutzt wird	steriles Leitungswasser (11° dH))
Produktprüfkonzentration	1,0%; 2,0% (V/V)
Aussehen der Produkte und ihrer Verdünnungen	klare Lösungen

Obligatorische Bedingungen:

Testorganismus:	Fusarium oxysporum (Cyclamen, Jungpflanzen)
Einwirkzeit	60 min, 240 min
Prüftemperatur	20°C ± 1°C
Belastungssubstanz	0,1 g lufttrockener Weißtorf (Korngrösse < 2 mm)

Prüfergebnisse

s. nachfolgende Tabelle

Schlußfolgerung

Für das Produkt **MENNO-Florades** wurde für die generelle Anwendung bei 20°C und 1 und 4 Stunden Kontaktzeit gemäß Richtlinie 16-4, Richtlinie für die Prüfung von Pflanzenschutzmitteln zur Desinfektion im Zierpflanzenbau (obligatorische Bedingungen) eine fungizide Konzentration gegenüber Fusarium oxysporum von

1,0% nach 4 Stunden Kontaktzeit und

2,0% nach 1 Stunde Kontaktzeit bestimmt.

Die Produkte Beispiel 6 (US-Patentschrift 4,414,1218, Spalte 10) und Beispiele 6e, 5d; 8, 10b (WO 96/11572) besitzen unter obligatorischen Bedingungen (s.o.) keine ausreichende Wirkung.

Technische Mikrobiologie
Dr. Jutta Höffler GmbH

Marion Korsch
(Versuchsdurchführung)

Hamburg, 2005-03-08

Christine Zimmermann
(Dipl. Biologin)

Wirksamkeit von MENNO-Florades (s.o.) und verschiedenen Formulierungen aus Patentschriften gegenüber Fusarium oxysporum (Prüfkeim der BBA- Richtlinie, S.2) im Keimträgerversuch mit Torfbelastung (BBA-Richtlinie)

		Re-Isolate von Fusarium oxysporum nach einer Einwirkungszeit von	
Desinfektionsmittel (Konz.)	Konz. %	1 Stunde	4 Stunden
Leitungswasser +Neutralisierungsmittel		3/3	3/3
Leitungswasser		3/3	3/3
Beispiel 6, US-Patentschrift 4,414,128, Spalte 10,	1,0%	3/3	2/3
	2,0%	3/3	2/3
Beispiel 5d, WO 96/11572	1,0%	3/3	3/3
	2,0%	3/3	3/3
Beispiel 6e, WO 96/11572	1,0%	3/3	3/3
	2,0%	3/3	3/3
Beispiel 8, WO 96/11572	1,0%	3/3	3/3
	2,0%	3/3	3/3
Beispiel 10b, WO 96/11572	1,0%	3/3	3/3
	2,0%	3/3	3/3
MENNO-Florades	1,0%	1/3	0/3
	2,0%	0/3	0/3

Legende: 0/3 = keiner von 3 Keimträgern bewachsen

1/3 = 1 von 3 Keimträgern bewachsen

2/3 = 2 von 3 Keimträgern bewachsen

3/3 = 3 von 3 Keimträgern bewachsen

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Exhibit D

Bacteriology, Mycology, Virology, Consultants

Sign of the company

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Test Report
Guideline* for the Testing of Plant Protectants for Disinfection in Ornamental Plant Cultivation
16-4

Orderer

MENNO CHEMIE-VERTRIEB GmbH
Langer Kamp 104
22850 Hamburg

Disinfectant samples

Product.....**MENNO-Florades**
(US pat.app. of PCT/EP9907151)

Lot no.....0004 of 09/07/2000

Manufacturer.....MENNO CHEMIE-VERTRIEB

Date of delivery 10/12/2000

Product formula/(US Pat.4,414,128).....**6**

Product formulas/(WO 96/11572).....**5d, 6e, 8, 10b**

Date of production.....02/19/2005

Supplier.....MENNO CHEMIE-VERTRIEB

Date of delivery 02/25/2005

Storage conditions.....ambient temperature

Appearance of the products: fluid, colorless

Active ingredient(s) .....organic acids, glycols

Concentration of use recommended by the manufacturer 1.0% - 2.0%

*issued by the Federal Biological Research Center for Agriculture and Forestry (Biologische Bundesanstalt für Land- und Forstwirtschaft, BBA)

Neutralization medium.....Polysorbate 80 (30g/L), Saponin (30/L)
Histidine (1g/L), Lecithin (3g/L)

Growth medium.....Potato Dextrose Agar (Oxoid)

Incubation temperature.....25°C ± 1°C

Test period .....2005-02-18 until 2005-03-04

Experimental conditions

Product diluent
in use at the test .....sterile tap water (196 mg/L $CaCO_3$)

Test concentration of the product .....1.0%; 2.0% (v/v)

Appearance of product and dilutions .....clear solutions

Obligatory conditions:

Test organism: .....Fusarium oxysporum
(cyclamen, young plants)

Active time .....60 min, 240 min

Test temperature .....20°C ± 1°C

Load substance .....0.1 g air-dry white peat
(particle size < 2 mm)

Test results

see the following table

Conclusion

For the product **MENNO-Florades**, a fungicidal concentration towards Fusarium oxysporum of

1.0% after 4 hours of contact and

2.0% after 1 hour of contact

was determined for general use at 20°C and 1 and 4 hours of contact time in accordance with guideline 16-4 for the testing of plant protectants for disinfection in ornamental plant cultivation (obligatory conditions).

The products example 6 (US patent specification 4,414,1218,row 10) and examples 6e, 5d; 8, 10b (WO 96/11572) do not have a sufficient effect under obligatory conditions (see above).

Technical Microbiology
Dr. Jutta Höffler GmbH

Hamburg, 2005-03-08

Marion Korsch
(Execution of the test)

Christine Zimmermann
(qualified biologist)

Hereby I certify the correctness and completeness of this translation of a test report from the German into the English language.

Schwarzenbek, March 14th, 2005

Dr. A. Lage

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